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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,151	11/25/2005	Yuwan Wang	P050002US	1882

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WANG & HO
66 HILLTOP ROAD
MILLINGTON, NJ 07946

EXAMINER	
SCHLIENTZ, NATHAN W	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/558,151	WANG ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 16-21 and 24-29 were cancelled and claims 22 and 23 were amended in an amendment filed 21 November 2008. As a result, claims 22 and 23 are examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 recites the limitation "said trichlorobutanol" in component (c). There is insufficient antecedent basis for this limitation in the claim. Claim 23 is dependent from claim 22 which states “local analgesics” in component (c), but does not recite “trichlorobutanol”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chen et al. (EP 0 535 734 A1) and Yamahira et al. (US 5,385,738).

Applicant's claims

Applicants claim a sustained release injection formulation comprising one or more avermectin at 0.5-30% w/v; hydrogenated castor oil at 0-10% w/v; a local analgesic at 0.5-3% w/v; BHT, BHA and/or propyl gallate at 0.2% w/v; and the remainder being dimethicone.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Chen et al. teach an injectable formulation comprising hydrogenated castor oil and an avermectin which has an unexpectedly long duration of activity (Abstract). Chen et al. teach that the hydrogenated castor oil imparts to the formulation an increased viscosity, and it appears that the increased viscosity together with the hydrophobicity of the carrier enable the injected formulation to remain at the injection site and form a depot of the active material which is slowly removed from the injection site over a prolonged period of time (pg. 2, ln. 21-24). Chen et al. teach that the avermectin compound is preferably abamectin or ivermectin, and is present at 0.5 to 10% w/v, preferably 2.5 to 5% w/v (pg. 3, ln. 10-12; and pg. 4, ln. 28-31); and that the hydrogenated castor oil is present at 0.5 to 3% w/v (pg. 4, ln. 6-10). Chen et al. further teach that in addition to the hydrogenated castor oil and avermectin, the formulation can contain an antioxidant such as propyl gallate, butylated hydroxytoluene, or butylated hydroxyanisole present at 0.01 to 2% w/v (pg. 4, ln. 32-35). Chen et al. provide an example wherein the formulation comprises 3.15% w/v ivermectin, 0.02% w/v n-propyl gallate, 1.5% w/v hydrogenated castor oil, and the remainder being glyceryl triacetate (pg. 4, ln. 50-55).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Chen et al. do not teach the formulation to comprise dimethicone and an analgesic. However, Yamahira et al. teach a sustained release injection formulation comprising an active ingredient and a pharmaceutically acceptable biodegradable carrier (i.e. gelatin) in a viscous solvent (i.e. silicone oil) for injection (Abstract; and col.

1, ll. 10-17 and 36-42). Also, Yamahira et al. teach that other conventional pharmaceutically acceptable additives may be added, such as local anesthetic agents (col. 4, ll. 43-59).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to add silicone oil (dimethicone) to the formulation of Chen et al. because Yamahira et al. teach silicone oil as a viscous solvent suitable for injection and Chen et al. teach that the viscous solvent creates a depot where the drug is slowly removed over a prolonged period of time. One of ordinary skill in the art would expect the viscous silicone oil would assist in forming the depot at the site of injection. Also, it would have been prima facie obvious to add an analgesic agent because Yamahira et al. teach that anesthetic agents are conventional pharmaceutical additives.

With regard to Applicants claiming 0.5-3% w/v of analgesic, one of ordinary skill in the art would have been able to determine the appropriate amount of a conventional additive readily used in compositions suitable for injection, as reasonably taught by Yamahira et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (EP 0 535 734 A1) and Yamahira et al. (US 5,385,738), further in view of Allwood (J. Applied Bacteriology, 1978).

Applicant's claims

Applicants claim a sustained release injection formulation comprising one or more avermectin at 1-10% w/v; hydrogenated castor oil at 1-5% w/v; trichlorobutanol at 0.5% w/v; BHT, BHA and/or propyl gallate at 0.2% w/v; and the remainder being dimethicone.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Chen et al. and Yamahira et al. are discussed above and incorporated herein by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Chen et al. and Yamahira et al. do not teach their injection formulations comprising trichlorobutanol. However, Allwood teaches that antimicrobial agents in sterile dosage forms have been included in injection formulations since before 1939, and their inclusion has been accepted as a reasonable practice (pg. Svii, 1st paragraph). Allwood further teaches that chlorbutol (trichlorobutanol) is recommended for inclusion at 0.5% w/v (Table 2).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to include trichlorobutanol at 0.5% w/v in the injection formulations of Chen et al. and Yamahira et al. because Allwood teaches that chlorbutol is recommended for inclusion in injection formulations.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616